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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT PAPER NUMBER

1645

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,043

Applicant(s)

HAKALEHTO, EINO ELIAS

Examiner

Khatol S Shahnan-Shah

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1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17, 19, 20, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17, 19, 20, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants' appeal brief, received September 13, 2004 is acknowledged.
2. Prosecution on the merits of this application is reopened on claims 14-17, 19, 20, 22 and 23.

The finality of the previous office action is hereby withdrawn.

3. Claims 14-17, 19, 20, 22 and 23 are pending and under consideration.

Prior Citations of Title 35 Sections

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Rejection Withdrawn

5. Rejection of claims 14-17, 19, 20, 22 and 23 under 35 U.S. C. 103(a), made in paragraph 16 of the office action mailed 4/09/2003 is withdrawn.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 14-17, 19, 20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thorns, C. J. et al. (US Patent Number 5,510,241) prior art already made of record, in view of Zawistowski, J. (US Patent Number 5,807,694).

Claims recite a method for detecting bacteria having fimbriae, comprising detecting

bacteria having fimbriae from a cultivation medium within the time period of 3 to 10 hours from the onset of cultivation, by detecting fimbrial antigens, which are, expressed soon after inoculation into the medium.

Thorn et al. teach a method for detecting for the presence of *Salmonella* species expressing fimbrial antigens, which have been grown on a selected medium. (see title and abstract and claims). Thorn et al. used a variety of liquid and solid media (see column 2, lines 25-65) and various temperature ranges from 22°C to 60° C (see columns 5 and 6). Thorn et al. teach detecting bacteria having fimbriae from a cultivation medium within the time period of 18 hours from the onset of cultivation (see column 7, example I). Thorn et al. also used direct binding and indirect ELISA methods. Thorn et al. further teach a method wherein the microbial antigens are detected with antibodies, which have been produced against synthetic peptides or a derivative thereof (see column 11 and claims). Thorn et al. also teach derivatives of the claimed synthetic peptide (see SEQ ID # 1, (i.e. amino acid 165-167) columns 26-28). Thorn et al. do not teach time period of 3 to 10 hours from the onset of cultivation

However, Zawistowski teach detection of *Salmonella* from eggs within a time period of 6 hours (see column 5, lines 15-65 and column 7, lines 1-7).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method of screening taught by Zawistowski and the method taught by Thorn et al. to obtain the instant disclosure. Given the fact that rapid screening methods for bacteria such as *Salmonella* are needed. One having ordinary skill in the art would have been motivated by expectation of success and the attainment of a better method to obtain a

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method which shortens the cultivation period as taught by Zawistowski for detecting bacteria such as *Salmonella* which are a major cause of food poisoning.

Conclusion

7. No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Thorne US patent 5,552,294.

New Horizon SMART II rapid test for detection of Salmonella.

SafePath E.coli 0157 Immunoassay Kit.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

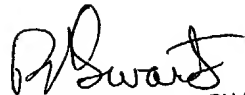


Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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November 27, 2003


RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER